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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/606,442	06/25/2003	George Baran	6298/431	2937

7590

04/06/2006

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EXAMINER

HILL, LAURA C

ART UNIT	PAPER NUMBER
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3761

DATE MAILED: 04/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/606,442	Applicant(s) BARAN, GEORGE	
	Examiner Laura C. Hill	Art Unit 3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 63-81 is/are pending in the application.
- 4a) Of the above claim(s) 63 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 64-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 25 June 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6/25/03, 11/29/04, 3/15/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. The species election requirement between Species I, claims 63-76 and Species II, claims 77-81 as discussed in the Office action dated 16 December 2005 is withdrawn upon further consideration.

2. However, a new restriction requirement is made as discussed below.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claim 63, drawn to a method of forming a catheter, classified in class 264, subclass 210.1.
- II. Claims 64-81, drawn to a method of forming a catheter, classified in class 264, subclass 210.1.

Inventions I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the tubing that forms the catheter does not require a j-shaped distal section. The subcombination has separate utility such as a nebulizing catheter for gas delivery only.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Kent Genin on 29 March 2006 a provisional election was made without traverse to prosecute the invention of Group II, claims 64-81. Affirmation of this election must be made by applicant in replying to this Office action. Claim 63 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Information Disclosure Statement

3. The information disclosure statement filed 25 June 2003 fails to comply with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609 because there is no explanation of relevance or English-language equivalent for any of the foreign patent documents on page 3. However, it is noted that the Examiner has still considered these references. It is also noted that there is a duplicate copy of EP 0587380 on page 3 of the information disclosure statement filed 25 June 2003.

4. The information disclosure statement filed 25 June 2003 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Specifically there are no copies provided in the current or related continuation applications for the Russian foreign patent numbers 185442 and 812296. The IDS has been placed in the application file, but the information referred to therein has not been considered as to the merits. Applicant is advised that the date of any re-submission of any item of information contained in this information disclosure statement or the

Art Unit: 3761

submission of any missing element(s) will be the date of submission for purposes of determining compliance with the requirements based on the time of filing the statement, including all certification requirements for statements under 37 CFR 1.97(e). See MPEP § 609.05(a).

5. It is noted that although no copies of Japanese Unexamined application publication no. S46-21488 and S59-186563 of the information disclosure statement dated 15 March 2004 have been provided in the current case, copies have been provided in parent case 09/265,603 and thus have been considered in accordance with MPEP 609.

Specification

6. The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

The following title is suggested: Method of Forming An Extruded Nebulizing Catheter with Orifices and Radiopaque Markings.

7. The disclosure is objected to because of the following informalities: it is unclear if the terms "I.D." and "O.D." referred to throughout the instant specification are intended to be the "inner diameter" and "outer diameter".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Art Unit: 3761

8. Claim 75 recites the limitation "the nebulization catheter" in line 2. There is insufficient antecedent basis for this limitation in the claim since the claim is dependent from (73 and 77) recites a 'catheter for nebulizing' in line 1.

9. Claim 76 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, claim 76 depends from withdrawn claim 63.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claim 77-81, 64-65, 67 and 76 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blake et al. (US 3,634,924; herein 'Blake') in view of Smith et al. (US 5,031,613; herein 'Smith'). Regarding claims 77-78, 64-65, 67, 76, and 81 Blake discloses a method of forming a multi-lumen flow-directed catheter produced by extrusion of a compliant thermoplastic material such as polyvinyl chloride having a

Art Unit: 3761

memory characteristic (column 1, lines 5-8, 30-32 and 73-75); the extrusion is cut off to the desired length and the end portion is heated and drawn (column 2, lines 1-9); and forming a plurality of orifices 33 pointing towards a proximal end and located at the distal end and sized to pass a liquid through one of the lumens (column 2, lines 66-68 and figure 6). Blake further discloses the catheter is not limited to use in veins and arteries but can be used elsewhere (column 1, lines 53-55). Blake *does not expressly disclose* the catheter is for nebulizing and providing an aerosol or the catheter has a j-shaped distal section. **Smith** discloses a nebulizing plastic catheter 2 having a j-shaped distal section made by thermo-forming process (column 1, lines 65-68, column 2, lines 10-15 and lines 34-39) with perforations 10 made in distal end (column 2, lines 13-16), said catheter provides medicinal aerosol particles which are inhaled into the lungs (column 3, lines 26-30). One would be motivated to modify the catheter of Blake with the j-shaped nebulizing catheter of Smith to provide a catheter useful in the lungs since both references are analogous art; plastic catheters with perforations. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter, thus providing a j-shaped nebulizing catheter.

Regarding claims 79-80 Blake/Smith disclose the j-shaped catheter as discussed above with respect to claim 77. Blake further discloses a round wire 30 is inserted in lumen 11 of the catheter so that the opening 11a will be formed and the shape of the catheter maintained (column 2, lines 38-47, figure 4).

11. Claim 66 is rejected under 35 U.S.C. 103(a) as being unpatentable over Blake et al. (US 3,634,924; herein 'Blake') in view of Smith et al. (US 5,031,613; herein 'Smith'),

Art Unit: 3761

and further in view of Boucher (US 3,561,444; herein 'Boucher'). Blake/Smith *do not expressly disclose* a portion is exposed to high-energy radiation. **Boucher** discloses ultrasonic nebulizers that produce aerosols with radiation (column 1, lines 4-11 and lines 44-46). One would be motivated to modify the nebulizing catheter of Blake/Smith with the radiation-exposed nebulizer of Boucher for improved performance since the references are in the same field of endeavor; nebulizers that provide aerosol treatment. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the catheter, thus providing a catheter exposed to high-energy radiation.

12. Claims 69-75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Blake et al. (US 3,634,924; herein 'Blake') in view of Smith et al. (US 5,031,613; herein 'Smith'), and further in view of Sheridan (US 2,857,915; herein 'Sheridan'). Regarding claims 69-74 Blake/Smith disclose the method of forming the catheter as discussed above with respect to claim 77. Smith discloses catheter 2 is provided with markings 14, which correspond to markings 16 on the endotracheal tube for improved positioning of the catheter (column 2, lines 57-67). Blake/Smith *do not expressly disclose* the markings are radiopaque stripes formed by a co-extrusion process. **Sheridan** discloses non-absorptive plastic catheter 2 with one or more inlet openings provided in the distal end 8 through which fluids may enter (column 2, lines 45-57 and 64-70, figure 1) having an opaque strip 18 running along the entire length of the catheter so as to permit the position of each and every portion of the catheter to be precisely determined within the living tissue for X-ray observation (column 2, lines 11-20), said opaque strip being

Art Unit: 3761

extruded through minor orifice 34 (column 3, lines 21-38). One would be motivated to modify the markings of Blake/Smith with the radiopaque extruded marking of Sheridan for improved catheter positioning since the references are analogous art; plastic catheters with orifices. Therefore, it would be obvious to one of ordinary skill in the art at the time the invention was made to modify the markings, thus providing co-extruded radiopaque markings.

Regarding claim 75 see the discussion above with respect to claims 73, 77 and 80.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Gonzalez (US 5,313,939) is cited for showing a J-shaped endotracheal multi-lumen catheter with apertures 13 at the distal end 5. Wray (US 3,370,112) is cited for showing passing plastic tubing through a heating zone at a temperature at or above its crystalline melting temperature for shape memory characteristics.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Hill whose telephone number is 571-272-7137. The examiner can normally be reached on Monday through Friday (off every other Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone

Art Unit: 3761

number for the organization where this application or proceeding is assigned is 571-273-8300.

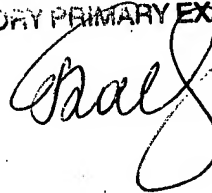
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Laura C. Hill
Examiner
Art Unit 3761

LCH



TATYANA ZALUKAEVA
SUPERVISORY PRIMARY EXAMINER





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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
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